K013877

DEC 1 9 2001

510(k) Summary

Submitter:

Codman and Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02780

Contact Person:

Kathryn Wunder
Phone Number: (508) 880-8351
Fax Number: (508) 828-3212

Date Prepared: November 21, 2001

Classification Name: Appliance, Fixation, Spinal Intervertebral Body

Proprietary Name: CODMAN SLIM-LOC™ System

Predicate Device: CODMAN Anterior Cervical Plate (ACP) System (K953730)

Intended Use: The CODMAN SLIM-LOC™ System is a permanent implant, generally indicated for short-term stabilization of the cervical spine from C2 to C7 employing screw fixation at the anterior face of the vertebral bodies. This product may be employed as an internal fixation device during the time interval required for arthrodesis.

Materials: Manufactured from ASTM F-136 implant grade titanium alloy.

Device Description: The CODMAN SLIM-LOC™ System consists of an assortment of implantable titanium alloy plates and screws. The plates have an integrated screw locking mechanism to prevent screw back out. A variety of cancellous screw types are provided for surgical convenience.

Performance Data: This submission relied upon appropriate biomechanical testing necessary to support the device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2001

Ms. Kathryn Wunder
Regulatory Affairs Specialist
Codman & Shurtleff, Incorporated
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K013877
Trade Name: Codman SLIM-LOC™ Anterior Plating System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: II
Product Code: KWQ
Dated: November 21, 2001
Received: November 23, 2001

Dear Ms. Wunder:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

page 1 of 1

510(k) Number (if known): **K013877**

Device Name
CODMAN® SLIM-LOC™ System

Indications for Use
The CODMAN SLIM-LOC™ System's plates and screws are permanent implants, generally indicated for stabilization of the cervical spine from C2 to C7 employing unicortical screw fixation at the anterior face of the vertebral bodies. This product may be employed as an internal fixation device during the time interval required for arthrodesis.

Specific clinical indications for anterior plating include:

Instability caused by trauma;

Instability associated with correction of cervical lordosis and kyphosis deformity;

Instability associated with pseudoarthrosis as a result of previously failed cervical spine surgery;

Instability associated with major reconstructive surgery for primary tumors or metastatic malignant tumors of the cervical spine;

Instability associated with single or multiple level corpectomy in advanced degenerative disk disease, spinal canal stenosis, and cervical myelopathy.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013877